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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,384	09/22/2003	Masayuki Yokoyama	S-2481/CONT	7495

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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT PAPER NUMBER

1618

DATE MAILED: 11/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/666,384	YOKOYAMA ET AL.	
	Examiner	Art Unit	
	James W. Rogers, Ph.D.	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 10, 11 and 13-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 10-11 and 13-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Amendment

The amendment to the claims filed 10/24/2006 has been entered

The declaration under 37 CFR 1.132 filed 10/24/2006 is insufficient to overcome the rejection of claims 1, 10-11, 14 and 16 as set forth in the last Office action because: the declaration only discloses that paclitaxel cannot be encapsulated by the micelles taught by the Ichiro reference, however one of the drugs encapsulated by the polymeric micelle specifically mentioned in Ichiro is camptothecin which is claimed by applicant along with paclitaxel, therefore the rejection still stands because Ichiro teaches at least one of the drugs claimed in the Markush group claimed by applicants. There was no evidence in the declaration that the Ichiro patent does not encapsulate camptothecin, all that applicants may have shown is that the Ichiro procedure to produce micelles may not encapsulate paclitaxel which is not the only species claimed in dependent claims 11, 14 and 16 all of which also claim camptothecin.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

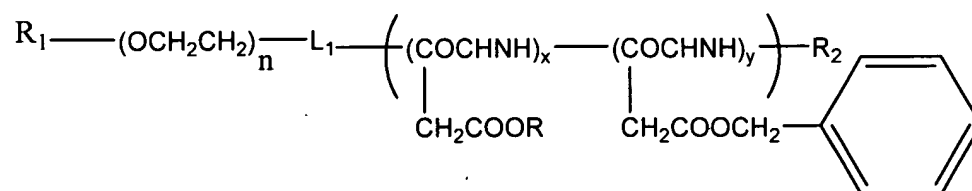
Claims 1,10-11 and 13-18 are rejected under 35 U.S.C. 102(b) as being unpatentable by Ichiro et al. (JP 11-335267), for the reasons set forth in the office action mailed 04/21/2006.

Applicant's arguments filed 9/30/2004 have been fully considered but they are not persuasive.

Applicants state that the block copolymers in Ichiro are only used in combination with KRN5500 in the examples, therefore there is no anticipation in regards to the drugs claimed by applicants.

The relevance of this assertion is unclear. Examples or experimental data are not limiting for the scope of an invention, clearly Ichiro specifically mentions that camptothecin is a preferred drug that can be encapsulated in the micelles taught within, therefore the limitation in claims 11,14 and 16 are met.

Applicants assert that Ichiro teaches a different block copolymer than applicants currently claimed invention because Ichiro teaches away from using a hydrogen moiety for R in the following polymer block:



Applicants state Ichiro teaches away from using a hydrogen in R because of Table 1 and Example 2 which do not disclose the use of hydrogen as the R group in the above block polymer.

Art Unit: 1618

The relevance of this assertion is unclear. Examples or experimental data are not limiting for the scope of an invention. Clearly all of the R groups in the above block copolymer are taught as being either a hydrogen or an aliphatic group as stated in the claims and in the body of the specification, therefore Ichiro does teach the same block copolymer as applicants currently claimed invention because R can be hydrogen.

Applicants also assert that Ichiro is silent on the method of making and that the examiner admitted this in the last office action. Applicants then assert that Ichiro teaches away from using a water non-miscible organic solvent as currently claimed by applicants.

Firstly the examiner never admitted that Ichiro is silent on the method of making, in fact in the first sentence of the 102(b) rejection in the previous office action the examiner states that Ichiro teaches how to produce the micelle composition, the examiner only stated latter in regards to the product by process limitations that "With regard to Claims 1,13-14, which are product by process claims, the product disclosed by the prior art is identical to the claimed product, even though (it is **made by a somewhat different process/the prior art is silent on the method of making**).

There is no evidence to show that the claimed process imparts any patentable distinction between the claimed product and that of the prior art." The examiner believes there is perhaps a slightly different process for making the micelles as argued by applicants in that the solvents encompassed within Ichiro and applicants currently claimed invention seem to be slightly different. Even if the solvents are slightly different in both inventions the organic solvent is removed so as to give drugs encapsulated by

Art Unit: 1618

polymer micelles with water as the solvent, the organic solvent(s) used in the preparation have no patentable weight because the two compositions are the same after removing the organic solvents and therefore they are not patentably distinct from one another. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

Applicants assert that Ichiro also requires a "dialysing treatment" which is not suitable for commercial manufacture or large-scale manufacture.

The relevance of this assertion is also unclear. As currently claimed applicants invention does not preclude additional steps in claim 1 because the phrase "comprising the steps of" does not preclude additional steps in the method of making, the transitional term "comprising", which is synonymous with "including", "containing", or "characterized by", is inclusive or open ended and does not exclude additional elements or method steps recited in the prior art. *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003). Applicants do not claim a process for production which is suitable for commercial manufacture or large-scale manufacture, this is not a limitation as currently claimed. In addition to this argument as disclosed in the previous office action dated 04/21/2006 and in the arguments above since claim 11 is a product by process claim, the method to remove the organic solvent was given no

patentable weight because, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Conclusion

No claims are allowed at this time.

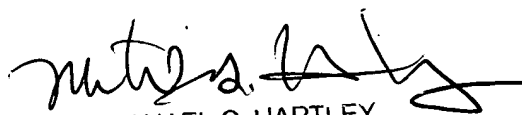
Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

Art Unit: 1618

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 572-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER